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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,580	08/20/2001	Sandor Szalma	MOLESIM.025A	5589
20995	7590	11/10/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			CLOW, LORI A.	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1631	

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/933,580

Applicant(s)

SZALMA ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/22/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' response, filed 16 August 2004, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 13-15 are currently pending. Claims 1-12 and 16-19 have been cancelled.

#### **Information Disclosure Statement**

The Information Disclosure Statement filed 22 January 2002, which has been re-submitted for consideration upon the Examiner's request, has been partially considered. The Yan et al. reference has not been considered because it lacks a publication date. A signed copy of PTO Form 1449 is included with this Office Action.

#### **Oath**

The new Oath filed 16 August 2004 is acceptable.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The text of the rejection can be found in the Office Action dated 18 May 2004.

### **Response to Applicant's Arguments**

Applicant argues that “the specification describes one way in which interaction fingerprints can be compared”. Applicant point the Examiner to page 8, lines 5-23 and Figure 5. This is not found persuasive. The Examiner clearly states in the previous Office Action that the specification “provides no exact details on just what the fingerprint values consist of and how they are generated”. As previously set forth, the specification states that the “protein/ligand interaction comparisons comprise identifying the nature of the ligand interaction with each protein in the comparison. Typically the protein/ligand interaction is characterized by a bonding affinity between each protein and each ligand. This could be binary or it could be a numerical value, such as an equilibrium binding constant or a binding energy (page 7, beginning line 20)”. It is not clear from the explanation in the specification just exactly what the fingerprint entails. Applicant points the Examiner to an example in which the fingerprint consists of a series of binary values, of which no definition of what these are made of is given other than to state they are vectors which represent binding between a test and a protein. However, it is unclear how the binding is ascertained such that a vector is generated. Does binding constitute affinity values, for instance? Further, Applicant states that an “overlap computation” is performed, which can be normalized, to represent proteins with similar chemical responses. There is no guidance in the specification regarding how to perform such an “overlap computation” nor how chemical

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similarity between two proteins indicate a target protein for pharmaceutical intervention. The claims do not recite that the first fingerprint is from a drug substrate for a particular disease, for instance.

Applicant goes on to argue that the specification enables one of skill in the art to generate interaction fingerprints for a plurality of proteins, compare those interaction fingerprints to determine the degree of overlap, and use the degree of overlap as an indication of the proteins' chemical similarity or dissimilarity. Applicant further argues that the protein with "least overlap" or the protein with "lowest average and/or maximum overlap" may be identified as a protein for pharmaceutical intervention. This is not persuasive in that the instant claims contain no limitations regarding generation of overlap nor do they contain limitations regarding similarity or dissimilarity. Further, there is no relation to overlap, similarity/dissimilarity and the "method of identifying a target protein for **pharmaceutical intervention**".

Applicant further states that "regions of fingerprints may be different" and that this somehow would identify a protein as suitable for pharmaceutical intervention. The specification does not explain what significance a difference in region would mean in terms of identifying a suitable protein for pharmaceutical intervention.

Applicant states that "high overlap of fingerprints of proteins can indicate that the proteins are members of the same functional family. Thus one of skill in the art would recognize that a protein could be identified as a target for pharmaceutical intervention if its interaction fingerprint had a high overlap with other proteins that had already been determined to be effective targets for pharmaceutical intervention". This is not persuasive in that the specification does not disclose how one would determine how high the overlap has to be to indicate members

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of the same functional family. Furthermore, the specification does not relate members of functional families to identification of target proteins for pharmaceutical intervention. If one protein is related to another, how does that indicate a target suitable for intervention?

Finally Applicant argues that the “enablement of claims 13-15 does not require teaching how to use interaction fingerprints and the binding affinities they represent in isolation to identify targets for pharmaceutical intervention”. This is not persuasive. In fact, the claims require that interaction fingerprints, which comprise a set of values representative of binding strength, be retrieved and compared in order to identify a target protein for pharmaceutical intervention. One of skill in the art would absolutely have to know how to use the fingerprints, which comprise binding strength, in order to make comparison and identify potential pharmaceutical targets.

For the reasons stated in the previous Office Action and the reasons stated above, the claims as recited are not enabled.

### **Conclusions**

The rejection of claim 16 under 35 USC 102(a) over Xenarios et al. has been withdrawn in view of Applicant’s amendment canceling claim 16.

Claims 13-15 remain rejected under 35 USC 112, 1<sup>st</sup> paragraph for lacking enablement.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center Number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*  
11/4/04

November 3, 2004  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*